

Appl. No. 10/791,592
Amdt. dated February 15, 2006
Reply to Office Action of November 15, 2005

PATENT

REMARKS/ARGUMENTS

The Applicants gratefully acknowledge that claims 13, 16 and 17 are subject to allowability. Upon entry of this amendment, claims 13, 14 and 16-19 will be pending in the application and presented for examination. Claims 1-12 and 15 have been canceled without prejudice. Claims 18 and 19 has been added. Entry of the amendment and allowance of claims 13, 14 and 16-19 are respectfully requested.

The Applicants thank the Examiner for her voice mail from January 19 in response to Applicants' inquiry. The Applicants' representative contacted the Examiner per phone on January 18 to inquire if a claim could be added to reflect original claim 1 (which included "an antibody or a binding fragment thereof"). The Examiner indicated in her voice mail that such a claim would be considered provided that the claim is drawn to "an antibody or a fragment thereof" and it is further specified in the claim that the fragment binds only to SEQ ID NO: 2. In response, the Applicants have added claims 18 and 19 and presented for the Examiner's review.

The Amendment

In order to expedite prosecution of the application and advance the case toward allowance, claim 15 has been canceled and new claims 18 and 19 have been added. No new matter was introduced by this amendment. New claims 18 and 19 are supported, for example, in paragraphs 0017 and 0018, wherein the MCP-1 antagonists (*e.g.*, antibodies) and fragments thereof are discussed.

The specification has been amended to correct the cross reference to related applications and to provide direct support for claim 14 as requested by the Examiner. Support for this amendment can be found in paragraphs 0084 and 0085 of the instant specification. Paragraph 0085 incorporates by reference U.S. Patent No. 5,194,375 which teaches the use of monoclonal antibodies to receptor proteins (see column 16, line 59 of the '987 specification).

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Priority

The Office Action indicates that support for an anti-MCP-1 antibody and a method of making the antibody can be found in the specification of the 08/182,962 application on lines 1-2, page 9, which discloses compositions for use in therapy, diagnosis, assay of MCP-1R, or in raising antibodies to MCP-1R, comprising effective amounts of MCP-1R proteins prepared according to the foregoing processes. The Office Action further indicates that support for the compositions comprising an antibody specific to MCP-1 can be found on lines 11-14, page 26 of the '962 application, reciting immunoassays using the anti-MCP-1 antibodies, and that the use of these antibodies for immunoassays would necessitate combining them with a pharmaceutically acceptable carrier, for example, PBS. The Office Action concludes that claims 13, 16 and 17, reciting an antibody specifically binding to MCP-1 receptor, a composition comprising an antibody, and a method of making the antibody are clearly contemplated in the '962 application and will therefore be given the priority date of January 13, 1994. Claims 14-15, drawn to a monoclonal antibody and a Fab antibody fragment, respectively, are given the priority date of July 25, 2000 in accordance with the parent application 09/625,573.

It is stated for the record that claim 14 (drawn to a monoclonal antibody of the MCP-1 receptor) should be assigned the priority date of January 13, 1995 in accordance with the parent application 08/446,669, now U.S. Patent No. 6,132,987 (herein the '987 patent). The '987 patent incorporates by reference U.S. Patent No. 5,194,375 which teaches the use of monoclonal antibodies for receptor proteins (see column 16, line 59 of the '987 specification). Please see below for a more detailed discussion (section under 102).

Specification

The specification is objected because of minor informalities. The Examiner requests correction of the *cross reference to related applications* which has been amended accordingly. The Examiner also requests that the specification be amended to provide direct support for claims 14 and 15.

The specification has been amended to provide direct support for a monoclonal antibody on page 23, paragraphs 0084 and 0085. No new matter was added by this amendment.

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Paragraphs 0084 and 0085 describe binding assays wherein monoclonal antibodies to a receptor protein can be used as antagonists. This is taught by the combination of the specification and U.S. Patent No. 5,194,375 which is incorporated by reference in paragraph 0085, and further incorporated by reference in the parent application 08/446,669, now U.S. Patent No. 6,132,987 (January 13, 1995). U.S. Patent No. 5,194,375 teaches the preparation of monoclonal antibodies drawn to receptor proteins in column 19, example 6, lines 56-66. (Please see below for a more detailed discussion of what the parent specification teaches.)

Since claim 15 has been canceled, this amendment to the specification is believed to be moot.

Rejection under 35 U.S.C. §112

The Office Action indicates that the rejections of canceled claims 1-5 and 9-12 under 35 U.S.C. §112, first paragraph, for new matter and written description, are withdrawn upon further consideration of the case. The Office Action further indicates that the rejections of canceled claims 1 and 11 under 35 U.S.C. §112, first paragraph, for enablement, are withdrawn upon further consideration of the case and in view of Applicants' arguments.

Rejection under 35 U.S.C. §102

The Office Action indicates that in reconsideration of the priority dates, the rejection of canceled claim 1 is withdrawn. However, the rejection of claims 2-5 and 9-12 under 35 U.S.C. §102(e), Wang *et al.*, U.S. Patent No. 6,723,520 (filed January 3, 2002; issued April 20, 2004) remains and is applied to new claims 14-15.

In order to advance the case toward allowance, claim 15 has been canceled. However, cancellation of claim 15 is not an acquiescence in the rejection. Claims 2-5 and 9-12 have previously been canceled.

With respect to claim 14, the rejection is believed to be moot since claim 14, drawn to monoclonal antibodies should be accorded the priority date of the parent application 08/446,669, now U.S. Patent No. 6,132,987 which is January 13, 1995 (see below for a more detailed discussion of what the parent specification teaches).

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The Office Action indicates that claims 14-15 are rejected under 35 U.S.C. §102(b) as being anticipated by Rodriguez-Frade *et al.* (March 1999). The Examiner indicates that Rodriguez-Frade *et al.* teach the use of monoclonal antibodies directed to MCP-1 receptor, CCR2.

The rejection is respectfully traversed.

As indicated above, claim 15 has been canceled. However, claim 14 drawn to a monoclonal antibody of MCP-1 receptor should be accorded the priority date of the parent application 08/446,669, now U.S. Patent No. 6,132,987 which is January 13, 1995 because the Applicants contemplated the use of monoclonal antibodies to MCP-1 receptor in 1995. As such, Rodriguez-Frade *et al.* do not anticipate claim 14.

This is evidenced by the instant specification, particularly paragraphs 0084 and 0085. The instant specification teaches the following in paragraphs 0084 and 0085:

[0084] The antagonist is identified by adding an effective amount of an organic compound to the culture medium used to propagate the cells expressing the N-terminal domain of MCP-1 receptor. An effective amount is a concentration sufficient to block the binding of MCP-1 to the receptor domain. The loss in binding of MCP-1 to the receptor may be assayed using various techniques, using intact cells or in solid-phase assays.

[0085] **For example, binding assays similar to those described for IL-7 in U.S. Pat. No. 5,194,375 may be used.** This type of assay would involve labelling MCP-1 and quantifying the amount of label bound by MCP-1 receptors in the presence and absence of the compound being tested. The label used may, for example, be a radiolabel, *e.g.*, ¹²⁵I or a fluorogenic label. [Emphasis added in bold.]

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U.S. Patent No. 5,194,375 which is incorporated by reference in paragraph 0085 states the following in column 19, Example 6, lines 56-66 of the specification:

Preparation of Monoclonal Antibodies to IL-7R

Preparations of purified recombinant IL-7R, for example, human IL-7R, or transfected COS cells expressing high levels of IL-7R are employed to generate monoclonal antibodies against IL-7R using conventional techniques, for example, those disclosed in U.S. Pat. No. 4,411,993. Such antibodies are likely to be useful in interfering with IL-7 binding to IL-7 receptors, for example, in ameliorating toxic or other undesired effects of IL-7, or as components of diagnostic or research assays for IL-7 or soluble IL-7 receptor. [Emphasis added in bold.]

Thus, it is clear from the specification (and parent specification) that the Applicants have contemplated the use of *monoclonal antibodies to MCP-1 receptor* in 1995. One of skill in the art would understand that the use of monoclonal antibodies as antagonists to MCP-1 receptor could be easily produced by following the teachings of U.S. Patent No. 5,194,375 and the conventional techniques of U.S. Pat. No. 4,411,993. Just as monoclonal antibodies are useful in interfering with IL-7 binding to IL-7 receptors, the same is true for monoclonal antibodies to MCP-1 receptor. Such monoclonal antibodies would interfere with MCP-1 ligand binding to MCP-1 receptors, thereby acting as antagonists. The Examiner is surely aware that the courts have repeatedly held that a "patent need not teach, and preferably omits, what is well known in the art" (*Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, 221 USPQ 481 (Fed. Cir. 1984)). Thus, the Applicants must not re-teach how to make monoclonal antibodies to a receptor protein if others have already taught so in the prior art. Since the Applicants were the first to contemplate monoclonal antibodies to MCP-1 receptor in 1995, Rodriguez-Frade *et al.* (March 1999) cannot anticipate the instant application.

In light of the above arguments, it is respectfully requested that the rejection of claim 14 under 35 U.S.C. §102(b) be withdrawn.

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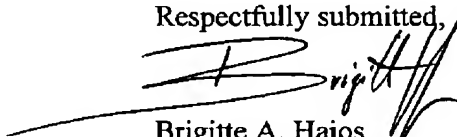
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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Attachments
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